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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,070	10/30/2003	Frederic J. Kaye	221749	1623

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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/698,070	Applicant(s) KAYE ET AL.	
	Examiner Tracy Vivlemore	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,35-43,45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 17 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43,45 and 46 is/are allowed.
- 6) ☒ Claim(s) 1-6,8-16,18-26 and 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection not reiterated in this Action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-16, 18-26, 35-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions that inhibit translation of a Mect1/MAML2 chimeric gene and comprise a fragment of a nucleic acid encoding SEQ ID NO: 12 and a nucleic acid complementary to the fragment having up to three mismatches, does not reasonably provide enablement for compositions wherein the nucleic acid complementary to the fragment comprises up to 10 base substitutions and inhibits translation of a Mect1/MAML2 chimeric gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors as enumerated *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), are considered when making a determination that a disclosure is not enabling: the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the

Art Unit: 1635

art, the amount of direction provided by the inventor, the existence of working examples and the quantity of experimentation needed to make the invention based on the content of the disclosure.

The claims are directed to compositions for inhibition of translation of a Mect1-MAML2 chimeric gene consisting essentially of a fragment of 17-32 nucleotides of a nucleic acid encoding SEQ ID NO: 12 and a nucleic acid complementary to this fragment; the claimed compositions are siRNAs. In specific embodiments the fragment is of varying lengths, the fragment and the nucleic acid are joined by a nucleic acid sequence recognized by a restriction enzyme, the chimeric gene results from a t(11:19) translocation, the fragment comprises SEQ ID NOs: 2 or 5, one of the sequences is in a vector or the composition forms a double stranded structure that comprises an overhang.

The specification describes the nucleic acid molecule complementary to the fragment at page 6. It is disclosed that this sequence can comprise base substitutions, but this term is not explicitly defined. Based on the entirety of this paragraph, which discloses the complementary strand can comprise substitutions, deletions, insertions, and/or inversions, and the disclosure that an alternative description of the complementary sequence is in terms of the percent identity between the complement and the fragment, the term base substitution is interpreted to refer to mismatches in the antisense strand of a siRNA. This interpretation is further supported by the disclosure in example 1 of a 29 base pair strand and that the second strand is a "near perfect" complement to those 29 bases. A mismatch in the complementary strand is a mismatch

Art Unit: 1635

in the antisense strand of a siRNA. The specification describes a working example wherein a composition having three mismatches effectively inhibited growth of H292 cells having the t(11:19) translocation associated with the Mect1/MAML2 chimeric gene of SEQ ID NO: 12 but had no effect on tumor cells lacking the t(11:19) translocation. The specification does not describe any other compositions having up to ten mismatches that inhibit translation of a Mect1/MAML2 chimeric gene.

The prior art teaches that a siRNA having up to ten mismatches in the antisense strand will not be functional. Amarzguioui et al. (Nucleic Acids Research 2003) describe the tolerance of siRNAs for mutations and chemical modifications. At page 590 Amarzguioui et al. teach that the presence of mutations (which create a mismatch between the antisense strand and the target) are location dependent, with those at the 3' end severely inhibiting activity. Saxena et al. (Journal of Biological Chemistry 2003) also describe the effects of antisense strand mismatches on siRNA activity. At column 1 of page 44314 Saxena et al. teach that siRNAs targeted to p21 that have 3-4 mismatches in the antisense strand are functional, however they do not function by mRNA degradation but through translation repression. Saxena et al. teach at column 2 of page 44314 that siRNAs targeted to geminin having three mismatches will decrease protein but not mRNA levels, while those having five or eleven mismatches do not function even through translation repression. Based on the teachings of the prior art that siRNAs with large numbers of mismatches in the antisense strand, especially when at the 3' end, do not reduce gene expression; and the lack of specific teachings in the specification regarding how to inhibit translation of a chimeric gene using siRNAs having

Art Unit: 1635

more than three such mismatches, the skilled artisan would not be able to use the claimed invention throughout its full scope without undue experimentation.

Allowable Subject Matter

Claims 40-43, 45 and 46 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

Art Unit: 1635

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
December 5, 2006

A handwritten signature in black ink, appearing to read "Tracy Vivlemore", is positioned below the typed name and title.